35 U.S.C. § 112 Rejection

Claims 18-31 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabled for an electrically permeable open cell construction, does not reasonably provide enablement for an actual means for pacing the heart. The Examiner asserts that the specification does not disclose the use of an implantable defibrillator operably connected to the cardiac jacket for pacing the heart, nor does it disclose pacing leads connected to the material of the jacket, and it does not disclose the number of pacing leads that are associated with the jacket.

Applicants respectfully assert that the Examiner has failed to state a *prima facie* case of enablement because the Examiner has failed to provide a properly reasoned and supported statement explaining any failure to comply with § 112. In other words, the Examiner has to establish a *prima facie* case of nonenablement based on evidence and/or technical reasoning. Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case because no evidence of nonenablement was offered.

Applicants respectfully assert that the specification does enable the claims throughout their scope. Cardiac pacing is a standard therapy to treat various disturbances of the heart. Applicants respectfully assert that the configuration and use of such systems were of general knowledge at the time of the invention. Therefore, Applicants assert that the specification in combination with the knowledge of those of skill in the art at the time of the invention would enable one of skill in the art to make and use the invention. Applicants therefore respectfully request that this rejection be withdrawn.

Applicants also assert that the specification complies with the written description portion of 35 U.S.C. § 112, first paragraph. The specification conveys clearly to those skilled in the art the information that the Applicants have invented the specific subject matter later claimed.

Obviousness-type Double Patenting Rejection

Claims 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,370,429. Although Applicants do not necessarily agree with the Examiner, in order to expedite prosecution of this application, avoid further erosion of the patent term, and

avoid the administrative burden of appeal, Applicants provide herewith an executed terminal disclaimer. Applicants respectfully request the withdrawal of this rejection.

Claims 23-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,169,922. Again, although Applicants do not necessarily agree with the Examiner, in order to expedite prosecution of this application, avoid further erosion of the patent term, and avoid the administrative burden of appeal, Applicants provide herewith an executed terminal disclaimer.

35 U.S.C. § 103 Rejection

Claims 20-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alferness ('343) in view of Moore. The Examiner asserts that since both Alferness and Moore disclose means for treating a disease of the heart, it would have been obvious to one of ordinary skill in the art to combine the devices of Alferness and Moore to obtain a kit for treating a disease of the heart.

Applicants respectfully assert that one of skill in the art would not have been motivated to combine the two devices in any way. The Alferness patent and this pending application are commonly assigned. The device of Alferness provides for reinforcement of the walls of the heart by constraining cardiac expansion. (abstract) The reinforcement that the device in Alferness provides is designed to counteract undesired cardiac expansion that can be caused by congestive heart failure, for example. Conversely, the device of Moore was developed to sense and control ventricular fibrillation (col. 1, lines 8-9). The sensing and control of ventricular fibrillation is necessary to monitor and treat episodes of ventricular fibrillation or hemodynamically unstable ventircular tachycardia (col. 1, lines 13-15). One of skill in the art would not have been motivated to combine the two devices, because although both treat the heart, the way in which they treat the heart and the problem that is being treated are entirely separate. The only suggestion to modify the teachings of Alferness appears to come from Applicants' currently pending disclosure, which is using impermissible hindsight.

Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn in view of the above comments.

Conclusion

In view of the comments presented herein, favorable reconsideration in the form of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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